

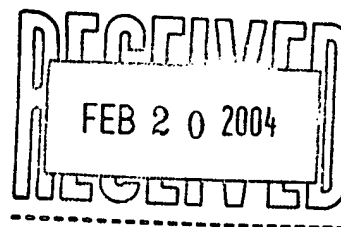
Express Mail No.: EL 984585652 US  
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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Paul L. DeAngelis ) Art Unit: 1632  
Serial No.: 09/842,484 )  
Filed: 04/25/2001 ) Examiner: M. Henry  
For: CHONDROITIN SYNTHASE GENE AND )  
METHODS OF MAKING AND USING )  
SAME )

Mail Stop Fee Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450



INFORMATION DISCLOSURE STATEMENT

List of Sections Forming Part of This  
Information Disclosure Statement

The following sections are being submitted for this Information Disclosure Statement:

1. ☒ Preliminary Statements
2. ☒ Form Substitute for 1449A/PTO
3. ☒ Statement as to Information Not Found in Patents or Publications
4. ☐ Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted
5. ☐ Cumulative Patents or Publications
6. ☒ Copies of Listed Information Items Accompanying this Statement

- 7.    ☐    Concise Explanation of Non-English Language Listed Information Items
  - 7A.   ☐    EPO Search Report
  - 7B.   ☐    English Language Version
- 8.    ☐    Translation(s) of Non-English Language Documents
- 9.    ☐    Concise Explanation of English Language Listed Information Items (Optional)
- 10.   ☒   Identification of Person(s) Making this Information Disclosure Statement

### **Section 1.            Preliminary Statements**

Applicants submit herewith patents, publications or other information of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 C.F.R. § 1.97(g)), an admission that the information cited is, or is considered to be, material to patentability or that no other material information exists.

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.

### **Section 2.            Form Substitute for 1449A/PTO**

☒    A completed Form Substitute for 1449A/PTO is attached hereto.

### **Section 3. Statement as to Information Not Found in Patents or Publications (Information Not Listed in Substitute for 1449A/PTO)**

The present invention relates to a chondroitin synthase gene and methods of making and using same. In more particular, but not by way of limitation, the present invention relates to a chondroitin synthase gene from *Pasteurella*

*multocida* and methods of isolating and using same. Additionally, the present invention relates to the use of unsulfated chondroitin and its preparation, as well as conversion into modified versions such as dermatan sulfate and chondroitin sulfate polymers.

**Section 4. Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted**

This application relies, under 35 U.S.C. § 120, on the earlier filing date of prior application Serial No. \_\_\_\_\_, filed on \_\_\_\_\_ (date).

*(complete the following, if applicable)*

[ ] This application also relies, under 35 U.S.C. 120, on the earlier filing date of prior application Serial No. \_\_\_\_\_, filed on \_\_\_\_\_ (date).

The following references were submitted to, and/or cited by, the Office in the prior application(s) and therefore, are not required to be provided in this application:

**Section 5. Cumulative Patents or Publications**

**STATEMENT**

\_\_\_\_\_ is cumulative of the following patents or publications listed on Form SB08A:

In accordance with 37 C.F.R. § 1.98(c), a copy of only \_\_\_\_ is being submitted with this Information Disclosure Statement.

**Section 6. Copies of Listed Information Items Accompanying this Statement**

Legible copies of all items listed in Form SB08A accompany this information disclosure statement.

☐ Exception(s) to above:

☐ Items in prior application from which an earlier filing date is claimed for this application, as identified in Section 4.

☐ Cumulative patents or publications identified in Section 5.

## **Section 7. Concise Explanation of Non-English Language Listed Information Items**

### **Section 7A. Concise Explanation of Non-English Language Listed Information Items - EPO Search Report**

The relevance with respect to the following citations listed on Form SB08A:

is submitted on the basis of accompanying:

*(check the appropriate item)*

☐ EPO search report that is in the English language,

☐ EPO search report that is not in the English language and that is accompanied also by an English language version of the EPO search report,

that issued on the corresponding European patent application.

### **Section 7B. Concise Explanation of Non-English Language Listed Information Items - English Language Version of EPO Search Report**

## **Section 8. Translation(s) of Non-English Language Documents**

☐ Submitted herewith is an English translation of the following foreign language patents, publications or information or of those portions

of those patents, publications or information considered to be material:

*(complete the following, if applicable)*

- ☐ No English language translations of the foreign language parents, publications or information or parts thereof are readily available, except for those listed above.
- ☐ The following foreign language documents submitted are believed to be the equivalent or substantial equivalent of the English language documents identified below, which are also submitted herewith.

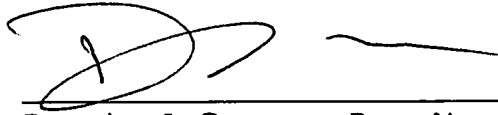
**Section 9. Concise Explanation of English Language Listed Information Items (OPTIONAL)**

**Section 10. Identification of Person(s) Making this INFORMATION DISCLOSURE STATEMENT**

The person making this statement is the agent/attorney who signs below on the basis of the information:

- ☐ supplied by the inventor(s)
- ☐ supplied by an individual associated with the filing and prosecution of this application (37 C.F.R. § 1.56(c)).
- ☒ in the agent/attorney's file

Respectfully submitted,

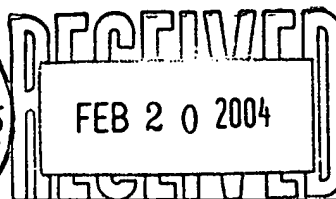
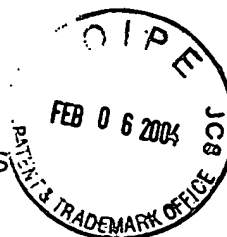
A handwritten signature in black ink, appearing to be 'D. Sorocco', written over a horizontal line.

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Date Deposited:

EL 984585652 US  
February 6, 2004



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Substitute for form 1449A/PTO

## SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Complete if Known	
Application Number	09/842,484
Filing Date	04/25/2001
First Named Inventor	Paul L. DeAngelis
Group Art Unit	1623
Examiner Name	Michael C. Henry
Attorney Docket Number	4605.003

### U. S. PATENT DOCUMENTS

EXAM INIT.	Cite No. 1	U.S. PATENT NUMBER Number	Kind Code <sup>2</sup> (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1	4585754		Meisner et al.	04/29/1986	
	2	20030100534		Zoppetti et al.	05/29/2003	

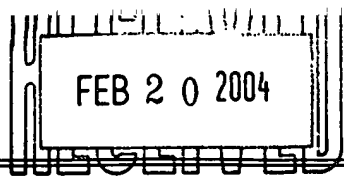
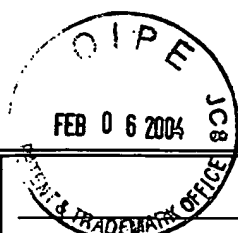
### FOREIGN PATENT DOCUMENTS

EXAM INIT.	Cite No. 1	Foreign Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office 3	Number 4	Kind Code <sup>5</sup> (if known)			
	A		EP 00300035		Beckwith	05/10/1995	
	B		WO 00/27437		Board of Regents of the University of Oklahoma	05/18/2000	
	C		WO 01/02597		Petrucchi et al.	01/11/2001	
	D		EP 01304338		Zoppetti	04/23/2003	

**U.S. and Foreign:** <sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard St.3). <sup>4</sup> Form Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard St. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

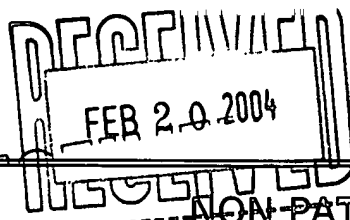
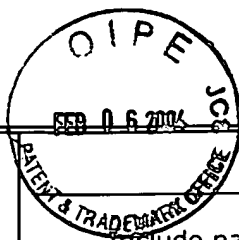
### NON PATENT DOCUMENTS

EXAM INIT.	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published
	AA	"GENETIC MAPPING OF THE K1 AND K4 ANTIGENS (L) OF ESCHERICHIA COLI. NON-ALLELISM OF K(L) ANTIGENS WITH K ANTIGENS OF O8:K27(A), O8:K8 (L) AND O9:K57 (B)", Orskov et al., Acta Pathol Microbiol Scand B, 84:125-131 (1976).
	AB	"DIFFERENCES IN THE EFFECTS OF pH ON THE HYDROLYTIC AND TRANSGALACTOSYLIC REACTIONS OF BETA-GALACTOSIDASE (ESCHERICHIA COLI)", Huber et al., Can. J. Biochem. Cell Biol., 61:198-206 (1983).
	AC	"BINDING AND REACTIVITY AT THE 'GLUCOSE' SITE OF GALACTOSYL-BETA-GALACTOSIDASE (ESCHERICHIA COLI)", Huber et al., Arch Biochem Biophys., 234: 151-160 (1984).

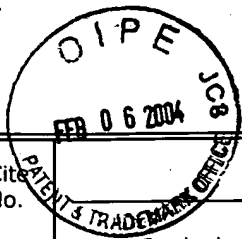


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	AD	"EFFECT OF REPLACING URIDINE 33 IN YEAST tRNAPhe ON THE REACTION WITH RIBOSOMES", Dix et al., J. Biol. Chem., 261(22):10112-8 (1986).
	AE	"STRUCTURE AND SEROLOGICAL CHARACTERISTICS OF THE CAPSULAR K4 ANTIGEN OF ESCHERICHIA COLI O5:K4:H4, A FRUCTOSE-CONTAINING POLYSACCHARIDE WITH A CHONDROITIN BACKBONE", Rodriguez et al., Eur. J. Biochem., 177:117-124 (1988).
	AF	"THE CARBOXY-TERMINAL DOMAIN OF THE LexA REPRESSOR OLIGOMERISES ESSENTIALLY AS THE ENTIRE PROTEIN", Schnarr et al., FEBS Lett., 234:56-60 (1988).
	AG	"A CRYPTIC FIMBRIAL GENE IN SERRATIA MARCESCENS", Moriya et al., J. Bacteriol., 171(12): 6629-36 (1989).
	AH	"MONOCLONAL ANTIBODIES SPECIFIC FOR K88ab, K88ac and K88ad ANTIGENS OF ESCHERICHIA COLI", Li et al., Wei Sheng Wu Xue Bao, 29:348-353 (1989) (FULL ARTICLE UNAVAILABLE; ABSTRACT ONLY).
	AI	"KINETIC CHARACTERIZATION OF THE UNISITE CATALYTIC PATHWAY OF SEVEN BETA-SUBUNIT MUTANT F1-ATPases FROM ESCHERICHIA COLI", al-Shawi et al., J. Biol. Chem., 264(26): 15376-83 (1989).
	AJ	"SLOW-BINDING INHIBITION OF THE ESCHERICHIA COLI PYRUVATE DEHYDROGENASE MULTIENZYME COMPLEX BY ACETYLPHOSPHINATE", Schonbrunn-Hanebeck et al., Biochemistry, 29(20): 4880-5 (1990).
	AK	"MOLECULAR CLONING AND EXPRESSION OF THE GENES ENCODING THE ESCHERICHIA COLI K4 CAPSULAR POLYSACCHARIDE, A FRUCTOSE-SUBSTITUTED CHONDROITIN", Drake et al., FEMS Microbiol. Lett., 54(1-3):227-30 (1990) (FULL ARTICLE UNAVAILABLE; ABSTRACT ONLY).
	AL	"ELECTRON MICROSCOPIC STUDY OF COEXPRESSION OF ADHESIVE PROTEIN CAPSULES AND POLYSACCHARIDE CAPSULES IN ESCHERICHIA COLI", Kronke et al., Infect. Immunity, 58:2710-4 (1991).
	AM	"TRANSPORT AND UTILIZATION OF FERROXAMINE-E-BOUND IRON IN ERWINIA HERBICOLA (Pantoea agglomerans)", Matzanke et al., Biol. Met., 181-185 (1991).
	AN	"MODULATION OF THE TIGHT BINDING OF CARBOXYARABINITOL 1, 5-BIPHOSPHATE TO THE LARGE SUBUNIT OF RIBULOSE 1,5-BISPHOSPHATE CARBOXYLASE/OXYGENASE", Smrcka et al., Arch. Biochem. Biophys., 286: 14-9 (1991).
	AO	"SLOW-ONSET INHIBITION OF RIBOSOMAL PEPTIDYLTRANSFERASE BY LINCOMYCIN", Kallia-Raftopoulos et al., Arch. Biochem. Biophys., 298: 332-339 (1992).
	AP	"ENHANCED CATALYSIS BY ACTIVE-SITE MUTAGENESIS AT ASPARTIC ACID 153 IN ESCHERICHIA COLI ALKALINE PHOSPHATASE", Matlin et al., Biochemistry, 31(35): 8196-8200 (1992).
	AQ	"A STUDY OF VITAMIN INHIBITION ON THE MUTAGENICITY OF THE ANTINEOPLASTIC DRUGS", Zhao and Huang, Zhonghua Yu Fang Yi Xue Za Zhi, 26:291-293 (1992) (FULL ARTICLE UNAVAILABLE; ABSTRACT ONLY).
	AR	"MOLECULAR CLONING OF A GENE CODING FOR BETA-GLUCANASE FROM BACILLUS SUBTILIS K4, ANTAGONIST TO PLANT PATHOGENIC FUNGI", Kim et al., RDA Journal of Agricultural Science Biotechnology, 35(1): 213-218 (1993).
	AS	"PRELIMINARY STUDY OF TEST METHODS TO ASSESS THE VIRUCIDAL ACTIVITY OF SKIN DISINFECTANTS USING POLIOVIRUS AND BACTERIOPHAGES", Davies et al., Journal of Hospital Infection, 25(2): 125-131 (1993).
	AT	"THE ESCHERICHIA COLI serA-LINKED CAPSULE LOCUS AND ITS FLANKING SEQUENCES ARE POLYMORPHIC, GENETIC EVIDENCE FOR THE EXISTENCE OF MORE THAN TWO GROUPS OF CAPSULE GENE CLUSTERS", Drake et al., J. Gen. Microbiol., 139 (Pt. 8): 1707-1714 (1993).
	AU	"REACTION OF MODIFIED AND UNMODIFIED tRNA (Tyr) SUBSTRATES WITH TYROSYL-tRNA SYNTHETASE (Bacillus stearothermophilus)", Avis et al., Biochemistry, 32(20): 5312-5320 (1993).
	AV	"EFFECT OF pH ON SOLUBILITY AND IONIC STATE OF LIPOPOLYSACCHARIDE OBTAINED FROM THE DEEP ROUGH MUTANT OF ESCHERICHIA COLI", Din et al., Biochemistry, 32(17): 4579-4586 (1993).
	AW	"AMINO ACID RESIDUES OF THE KRINGLE-4 AND KRINGLE-5 DOMAINS OF HUMAN PLASMINOGEN THAT STABILIZE THEIR INTERACTIONS WITH OMEGA-AMINO ACID LIGANDS", McCance et al., J. Biol. Chem., 269(51):32405-32410 (1994).
	AX	"KINETIC MECHANISM OF KINESIN MOTOR DOMAIN". Ma and Taylor. Biochemistry. 34(40): 13233-13241 (1995).





EXAM INIT.	Cite No.	NON-PATENT DOCUMENTS
		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published
	AY	"PRODUCTION AND PURIFICATION OF AN EXTRACELLULARLY PRODUCED K4 POLYSACCHARIDE FROM ESCHERICHIA COLI", Manzoni et al., Biotechnol. Lett., 18(4): 383-386 (1996).
	AZ	"A NOVEL FAMILY OF PHOSPHOLIPASE D HOMOLOGUES THAT INCLUDES PHOSPHOLIPID SYNTHASES AND PUTATIVE ENDONUCLEASES: IDENTIFICATION OF DUPLICATED REPEATS AND POTENTIAL ACTIVE SITE RESIDUES", Ponting and Kerr, Protein Science, 914-922 (May 1996).
	BA	"BIOSYNTHESIS OF DERMATAN SULPHATE. DEFRUCTOSYLATED ESCHERICHIA COLI K4 CAPSULAR POLYSACCHARIDE AS A SUBSTRATE FOR THE D-GLUCURONYL C-5 EPIMERASE, AND AN INDICATION OF A TWO-BASE REACTION MECHANISM", Hannesson et al., Biochem. J., 313(Pt. 2): 589-596 (1996).
	BB	"BIOSYNTHESIS OF THE ESCHERICHIA COLI K4 CAPSULE POLYSACCHARIDE: A PARALLEL SYSTEM FOR STUDIES OF GLYCOSYLTRANSFERASES IN CHONDROITIN FORMATION", Lidholt et al., J. Biol. Chem., 272(5):2682-2687 (1997).
	BC	"KINETIC MECHANISM OF MONOMERIC NON-CLARET DISJUNCTIONAL PROTEIN (Ncd) ATPase", Pechatnikova et al., J. Biol. Chem., 272(49): 30735-30740 (1997).
	BD	"A TWO-SITE MECHANISM FOR ATP HYDROLYSIS BY THE ASYMMETRIC REP DIMER P2S AS REVEALED BY SITE-SPECIFIC INHIBITION WITH ADP-A1F4", Wong and Lohman, Biochemistry, 36(11): 3115-3125 (1997).
	BE	"THE CAPSULE BIOSYNTHETIC LOCUS OF PASTURELLA MULTOCIDA A:1", Chung et al., FEMS Microbiology Letters, 186:289-296 (1998).
	BF	"ROLE OF FIMBRIAE-MEDIATED ADHERENCE FOR NEUTROPHIL MIGRATION ACROSS ESCHERICHIA COLI-INFECTED EPITHELIAL CELL LAYERS", Godaly et al., Molecular Microbiology, 30(4): 725-735 (1998).
	BG	"COMPLETE KINETIC MECHANISM OF ELONGATION FACTOR Tu-DEPENDENT BINDING OF AMINOACYL-tRNA TO THE A SITE OF THE E. COLI RIBOSOME", Pape et al., EMBO J., 17(24): 7490-7497 (1998).
	BH	"TRANSFER RNA IDENTITY CONTRIBUTES TO TRANSITION STATE STABILIZATION DURING AMINOACYL-tRNA SYNTHESIS", Ibba et al., Nucleic Acids Research, 27(18):3631-3637 (1999).
	BI	"CONTRACTILE FUNCTION AND MYOPLASMIC FREE Ca <sup>2+</sup> (Cam) IN CORONARY AND MESENTERIC ARTERIES OF ENDOTOXEMIC GUINEA PIGS", Jones et al., Shock, 11: 64-71 (1999).
	BJ	"KINETIC STUDIES ON THE INTERACTION BETWEEN A RIBOSOMAL COMPLEX ACTIVE IN PEPTIDE BOND FORMATION AND THE MACROLIDE ANTIBIOTICS TYLOSIN AND ERYTHROMYCIN", Dinos et al., Biochemistry, 39(38): 11621-11628 (2000).
	BK	"STRUCTURE-FUNCTION RELATIONSHIPS IN NOVEL PEPTIDE DODECAMERS WITH BROAD-SPECTRUM BACTERICIDAL AND ENDOTOXIN-NEUTRALIZING ACTIVITIES", Mayo et al., Biochemical Journal, 349(3): 717-728 (2000).
	BL	"RING OPENING IS NOT RATE-LIMITING IN THE GTP CYCLOHYDROLASE I REACTION", Bacher et al., J. Biol. Chem., 276(4): 2622-2626 (2001).
	BM	"SUBUNIT COMMUNICATION IN TETRAMERIC CLASS 2 HUMAN LIVER ALDEHYDE DEHYDROGENASE AS THE BASIS FOR HALF-OF-THE-SITE REACTIVITY AND THE DOMINANCE OF THE ORIENTAL SUBUNIT IN A HETEROTETRAMER", Weiner et al., Chemico-Biological Interactions, 130-132(1-3):47-56 (2001).
	BN	"DETECTION OF SUBMICROGRAM QUANTITIES OF GLYCOSAMINOGLYCANS ON AGAROSE GELS BY SEQUENTIAL STAINING WITH TOLUIDINE BLUE AND STAINS-ALL", Volpi and Maccari, Electrophoresis, 23(24):4060-4066 (2002).
	BO	"STRUCTURAL/FUNCTIONAL CHARACTERIZATION OF THE ALPHA 2-PLASMIN INHIBITOR C-TERMINAL PEPTIDE", Frank et al., Biochemistry, 42:1078-1085 (2003).
	BP	"Trp-999 OF BETA-GALACTOSIDASE (ESCHERICHIA COLI) IS A KEY RESIDUE FOR BINDING, CATALYSIS, AND SYNTHESIS OF ALLOLACTOSE, THE NATURAL LAC OPERON INDUCER", Huber et al., Biochemistry, 42(6): 1796-1803 (2003).
	BQ	"SEPARATION OF CAPSULAR POLYSACCHARIDE K4 AND DEFRUCTOSYLATED K4 DERIVED DISACCHARIDES BY HIGH-PERFORMANCE CAPILLARY ELECTROPHORESIS AND HIGH-PERFORMANCE LIQUID CHROMATOGRAPHY", Volpi, Electrophoresis, 24(6): 1063-1068 (2003).
	BR	"MILLIGRAM-SCALE PREPARATION AND PURIFICATION OF OLIGOSACCHARIDES OF DEFINED LENGTH POSSESSING THE STRUCTURE OF CHONDROITIN FROM DEFRUCTOSYLATED CAPSULAR POLYSACCHARIDE K4", Volpi, Glycobiology, 13(9):635-640 (2003).



EXAM INIT.	Cite No.	<b>NON PATENT DOCUMENTS</b>	
		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	
<b>Non Patent Documents:</b> <sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.			
Examiner Signature:		Date Considered:	
EXAMINER: Initial if citation considered, whether or not citation is in conformance and not considered. Include copy of this form with next communication to applicant. **Place of Publication refers to name of publication in which the information was published.			

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